JIM GIBBONS
Governor

STATE OF NEVADA
DEPARTMENT OF HUMAN RESOURCES
DIVISION OF HEALTH CARE FINANCING AND POLICY
NEVADA MEDICAID
PHARMACY & THERAPEUTICS COMMITTEE

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401 So. Carson Street, Room 3137
Carson City, Nevada 89701

Meeting Minutes
September 23, 2010

Committee Members Present
Las Vegas: Rudy Manthei, MD; Joseph Adashek, MD; Weldon Havins, MD; Constance Kalinowski, MD; Shamim Nagy, MD
Carson City: Judy Britt, Pharm.D.; David Chan, R.Ph.

Others Present
DHCFP:
Las Vegas: Gabriel Lither, Deputy Attorney General
Carson City: Jennifer Matus, Pharmacy Program Specialist

Magellan Medicaid Administration:
Las Vegas: Rob Coppola, Pharm.D, Program Director; Paula Townsend Pharm.D., Clinical Manager; Shirley Hunting
Carson City: Judy LaFleur

Others:
Las Vegas: Don Robinson-Baxter; Casey Wood-Pfizer; Irene Camerino-Forest; Ronnie DePue-Forest; Lori Howarth-Bayer; Deborah Wafer-Gilead; Sandy Sierawski-Pfizer; Michael Pinocci-Pfizer; John Brokars-Lilly; Helen Liao-Lilly; Dan Bay-Abbott; Karen Santilla-Astra Zeneca; Larry Hinson-Astra Zeneca; Steve Fox-Glaxo Smith Kline; Ken Grant, MD; Bradford Gidding-Pfizer; Jane Stephen-Allergan.

Carson City: Chris Almeida-Purdue; Sabrina Aery-Bristol Myers Squibb; Tammy Egger-BMS; Jeff Scheneman-Pfizer; Diane Smith.

Copies of written testimony submitted by the public were distributed to the committee.

I. Call to Order and Roll Call

Chairman Rudy Manthei called the meeting to order at 1:03 p.m.

II. Review and Approval of the June 24, 2010 Meeting Minutes

MOTION: Joseph Adashek motioned to approve the minutes as presented.
SECOND: Weldon Havins
VOTES: Unanimous
MOTION CARRIED

Rob Coppola reported that in August, 2009, First Health Services was purchased by Magellan Health Systems. As a condition of that agreement with Coventry, the previous owner, First Health was required to change their name within one year. Effective August 1, 2010, the name was changed to Magellan Medicaid Administration.

III. New Drug Class Reviews

A. NSRIs for Fibromyalgia

Public Comment

Dr. Ken Grant, rheumatologist, currently affiliated with Touro University, previously with the University of Nevada-Las Vegas, requested free access to the FDA-approved medications for fibromyalgia. He has prescribed all of the medications being discussed and has found in his experience that no one medication works for all patients. There are differences between all the medications in terms of safety and side effects, however, Lyrica® seems to have fewer and less serious side effects according to the package insert compared to the other medications. He prescribes Cymbalta® as a last choice due to more interactions with other medications and based on his experience, does not recommend combining SNRI medications.

Diane Smith stated that she suffers from fibromyalgia. Her condition was misdiagnosed for many years. She underwent many tests and was prescribed multiple medications, many which were not effective. Once diagnosed, her physician prescribed a medication for fibromyalgia and her condition improved. She requested consideration be given to keeping treatments simple with open and equal access to all patients.

Drug Class Review Presentation – Magellan Medicaid Administration

Rob Coppola stated that DHCFP and Magellan Medicaid recommend this item be tabled for a future meeting. When the agenda was posted, there was confusion among the stakeholders regarding what drugs were going to be presented in this class. There were also contractual issues involving clinical edits that were put in place whether on specific drugs within the class or on the class as a whole. As a result, Magellan is not able to make a preferred drug recommendation at this time.

Committee Discussion and Action to Approve Clinical/Therapeutic Equivalency of Agents in Class and to Identify Exclusions/Exceptions for Certain Patient Populations

MOTION: **Weldon Havins motioned to table this item until the next meeting.**
SECOND: **Shamim Nagy**
VOTES: **Unanimous**
MOTION CARRIED

Dr. Manthei asked if the agents in this class are currently available. Dr. Coppola replied that there is an edit in place for the drugs in this class which requires an ICD-9 for fibromyalgia be documented on the prescription and submitted on the claim.

B. Antivirals for Influenza

Public Comment

No comment.

Drug Class Review Presentation – Magellan Medicaid Administration

Dr. Townsend stated that the antivirals for influenza are being presented as a proposed new therapeutic class to be added to the PDL. There are two pharmacological classes: 1) adamantanes for Influenza A which consist of amantadine (Symmetrel®) and the closely related rimantadine (Flumadine®) with similar properties and 2) neuraminidase inhibitors for Influenza A and B consisting of oseltamivir (Tamiflu®) which is the oral pro drug and zanamivir (Relenza®) which is the inhaled active drug. All four have both prophylactic and treatment indications. The difference in ages for whom these drugs are approved is most significant with the neuraminidase inhibitors. Tamiflu® can be used in children as young as one year old (the FDA has granted emergency use authorization for children less than one year old). Relenza® is limited to children greater than five years old and for patients without respiratory disorders or lactose sensitivity.

Patients must be able to effectively use the inhaler. The CDC annually recommends the drug of choice based on sensitivity of the predominant influenza strain. Although resistance to these drugs is similar among agents within each class, it is not always the case. In 2009, strains of H1N1 with resistance to Tamiflu® due to the H275Y mutation were not resistant to Relenza®. Comparative trials show that when the virus is susceptible, efficacy is similar among the drugs within each group. Adverse reactions vary among drugs requiring an option be available. It is the recommendation of DHCFP and Magellan Medicaid Administration that the agents in this class be considered therapeutic alternatives.

Committee Discussion and Action to Approve Clinical/Therapeutic Equivalency of Agents in Class and to Identify Exclusions/Exceptions for Certain Patient Groups

MOTION: Shamim Nagy motioned that the agents in this class be considered therapeutic alternatives.
SECOND: Weldon Havins
VOTES: Unanimous
MOTION CARRIED

Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by Magellan Medicaid Administration and the Division of Health Care Financing and Policy

Dr. Townsend stated that it is the recommendation of DHCFP and Magellan Medicaid Administration to add all four agents, generic amantadine, generic rimantadine, Tamiflu® and Relenza®, to the PDL

Committee Discussion and Approval of Drugs for Inclusion on the PDL

MOTION: Weldon Havins motioned to add the four agents, generic amantadine, generic rimantadine, Tamiflu® and Relenza®, to the PDL.
SECOND: Joseph Adashek
VOTES: Unanimous
MOTION CARRIED

IV. Established Drug Class Reviews

A. Platelet Aggregation Inhibitors

Public Comment

Tammy Egger, Bristol Myers Squibb, spoke in support of Plavix®. Plavix® has a broad indication for use and was FDA-approved over a decade ago. The patent will expire in November, 2011. It's indicated for patients with a history of recent myocardial infarction (MI), recent stroke, established peripheral arterial disease (PAD) and acute coronary syndrome (ACS). Plavix® is supported by guidelines from the American Cardiology and American Heart Associations for stroke, ACS and PAD. There is a box warning for diminished effectiveness in poor metabolizers. Tests are available to identify a patient's CYP2C19 genotype and can be used as an aid in determining therapeutic treatment. There has also been a recent label change regarding the PPI drug interaction and that omeprazole be monitored to CYP2C19 inhibitor. Pantoprazole is a weak CYP2C29 inhibitor with less CYP2C19 inhibitory activity than omeprazole. There is no dichotomy separation from responder versus non-responder.

John Brokars, Lilly, spoke in support of Effient®, requesting it be added to the PDL for use in acute coronary syndrome patients. There is a black box warning for bleeding risk and it's not recommended for patients greater than 75 years of age or less than 60 kg or in patients with a history of stroke. Effient® is indicated in acute coronary syndrome in patients with unstable angina or non-ST-elevation myocardial infarction. Initial treatment is a 60mg loading dose then 10mg once daily or 5mg in patients less than 60kg. Effient ® is a P2Y12 platelet inhibitor. Unlike clopidogrel, parsugrel is not significantly affected by genetic variations that reduce CYP2C19 enzymes. There is no labeled warning with regards to CYP2C19 genotype. Also, unlike clopidogrel, there is no drug-drug interaction warning against the use of parsugrel with

proton pump inhibitors (omeprazole). In a study of 13,806 patients comparing Effient® to Plavix®, there was an overall 19% risk reduction for the primary composite endpoint of CV death, nonfatal MI, or nonfatal stroke. In patients with diabetes, there was a 30% risk reduction for the primary composite endpoint). In a study of 11,000 which included patients ≥75 years of age, the risk of bleeding increased with advancing age although the relative risk of bleeding was similar across age groups. For patients who are discharged post PCI, and those receiving Effient® while hospitalized, he requested continuation of Effient® therapy. He requested that Effient® be included on the PDL.

Dr. Nagy asked if bleeding is dose related. Mr. Brokars replied that the bleeding is more specific to patients older than 75, less than 60kg or had a previous stroke.

Drug Class Review Presentation – Magellan Medicaid Administration

Dr. Townsend stated that this is an existing class on PDL. A new drug in this class, prasugrel (Effient®), has been on the market for a year. Current drugs on the PDL include Aggrenox® indicated for the prevention of stroke; dypyridamole for valve replacement; and aspirin. Clopidogrel (Plavix®) is also on the PDL and is indicated for secondary prevention of atherosclerotic events in patients with recent stroke, MI or established PVD. It is also indicated in ACS including ST-elevation acute MI and non-Q-wave acute MI or unstable angina during medical management or PCI (with/without stenting). Prasugrel is a thienopyridine class inhibitor of platelet activation similar to clopidogrel. It has a narrow indication of ACS managed with PCI. Relative to clopidogrel, the principal risk with prasugrel is bleeding risk and the principal benefit is the prevention of non-fatal MI. The overall population benefit in terms of absolute risk reduction is 2.1% for the composite endpoint driven by reduced risk of non-fatal MI. Risk reduction in the overall population for the composite endpoint was 9.4% versus 11.5%. In the FDA analysis of bleeding risk in the non-CABG population per 1,000 patients treated, they calculate 30 excess TIMI bleeding events of any magnitude; 4.3 life-threatening TIMI bleeds; 10.5 bleeding events associated with a decrease in hemoglobin of ≥3 g/dL; and 5.1 bleeding events associated with a decrease in hemoglobin of ≥5 g/dL. It is the recommendation of DHCFP and Magellan Medicaid Administration that clopidogrel (Plavix®) and prasugrel (Effient®) be considered therapeutic alternatives.

Committee Discussion and Action to Approve Clinical/Therapeutic Equivalency of Agents in Class and to Identify Exclusions/Exceptions for Certain Patient Groups

Dr. Manthei noted that the Committee has received letters of testimony supporting the addition of Effient® to the PDL.

MOTION: **Joseph Adashek motioned that clopidogrel and prasugrel be considered therapeutic alternatives.**
SECOND: **Weldon Havins**
VOTES: **Unanimous**
MOTION CARRIED

Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by Magellan Medicaid Administration and the Division of Health Care Financing and Policy

Dr. Townsend stated that it is the recommendation of DHCFP and Magellan Medicaid Administration that no changes be made to the PDL. Aggrenox®, aspirin, dipyridamole and Plavix® will remain the preferred agents.

Committee Discussion and Approval of Drugs for Inclusion on the PDL

Dr. Havins asked for clarification that the recommendation does not include the addition of Effient® for ACS as a preferred drug. Dr. Townsend replied that the recommendation does not include Effient® as a preferred agent.

Dr. Coppola reminded the Committee that for unique indications, the non-preferred drug can be obtained through the prior authorization process (PA).

MOTION: **Joseph Adashek motioned to accept Magellan's recommendation that Aggrenox®, aspirin, dipyridamole and Plavix® continue to be preferred agents and to add Effient® for the indication of ACS with PCI.**
SECOND: **Weldon Havins**
VOTES: **Unanimous**
MOTION CARRIED

B. Ophthalmic Anti-inflammatory Agents

Public Comment

No comment.

Drug Class Review Presentation – Magellan Medicaid Administration

Dr. Townsend stated that this is an existing class on the PDL in which a new product has been released. Corticosteroids are not a managed class of anti-inflammatories and are available with equal status; only the NSAIDs are being reviewed. Current agents on the PDL are Ketoprofen (Acular® and Acular® LS which contain BAK .01 as a preservative; diclofenac (Voltaren®) with preservative sorbic acid; flurbiprofen (Ocufen®) with preservative thimerosal; nepafenac (Nevanac®) with preservative BAK .005 (the lowest concentration on the market). The formulation of ketoprofen (Acuvail®) has been brought to market as preservative-free and is packaged in single use vials for pain and inflammation following cataract surgery. This is short-term therapy, less than 14 days. The NSAIDs have the potential for severe corneal adverse events when used long term. Adverse events related to the preservative BAK, are primarily reported with long-term therapy. Toxicity to the cornea with BAK is thought to be time and concentration dependent and may be important with long-term therapy such as with drugs for glaucoma. There are no studies comparing the new Acuvail® product to any of the other NSAID products, only to the vehicle. It is the recommendation of DHCFP and Magellan Medicaid Administration that the agents in this class be considered therapeutic alternatives.

Committee Discussion and Action to Approve Clinical/Therapeutic Equivalency of Agents in Class and to Identify Exclusions/Exceptions for Certain Patient Groups

MOTION: **Weldon Havins motioned that the topical NSAID agents in this class be considered therapeutic alternatives.**
SECOND: **Joseph Adashek**
VOTES: **Unanimous**
MOTION CARRIED

Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by Magellan Medicaid Administration and the Division of Health Care Financing and Policy

Dr. Townsend stated that it is the recommendation of DHCFP and Magellan Medicaid Administration that no changes be made to the PDL with Acular®, Acular® LS, diclofenac, flubiprofen and Nevanac® being the preferred agents.

Committee Discussion and Approval of Drugs for Inclusion on the PDL

MOTION: **Joseph Adashek motioned to accept Magellan Medicaid Administration's recommendation that no changes be made to the PDL in this class.**
SECOND: **Shamim Nagy**
VOTES: **Unanimous**
MOTION CARRIED

V. Preferred Drug List: Class Name Changes

Public Comment

No comment.

Proposed Drug Class Name Changes

Dr. Manthei requested that Magellan present the proposed changes prior to a call for public comment in order for the public to be made aware of the proposed changes. A handout listing the proposed changes was available for public review at the meeting.

Dr. Townsend stated that there are several classes on the PDL that are being proposed for name change primarily for clarity, consistency and provider ease of finding the products on the list. The proposed changes will place agents with similar indications close to one another on the PDL.

Recommendations are:

Current Class Name	Proposed New Class Name
Multiple Sclerosis Agents	-Multiple Sclerosis Agents: Disease Modifying -Multiple Sclerosis Agents: MS Specific Symptomatic Treatment
Respiratory: Inhaled Corticosteroids/Nebs	-Respiratory: Inhaled Corticosteroid/Beta-Adrenergic Combinations -Respiratory: Inhaled Corticosteroids/Nebs
Direct Renin Inhibitors	-Cardiovascular: Direct Renin Inhibitors and Combinations
Intranasal Rhinitis Agents	-Respiratory: Intranasal Rhinitis Agents

Committee Discussion and Approval of PDL Drug Class Name Changes

MOTION: **David Chan motioned to accept Magellan's recommendation to change the class names as presented.**
SECOND: **Weldon Havins**
VOTES: **Unanimous**
MOTION CARRIED

VI. Report by Magellan Medicaid Administration on New Drugs to Market, New Generic Drugs to Market, and New Line Extensions

Dr. Townsend presented the report for committee review.

VII. Review of Next Meeting Location, Date, and Time

The next meeting is scheduled for December 16, 2010, at the Las Vegas Chamber of Commerce with videoconferencing to the Magellan Medicaid Administration office in Reno.

VIII. Public Comment

No comment.

IX. Adjournment

MOTION: **Joseph Adashek motioned for adjournment.**
SECOND: **Weldon Havins**
VOTES: **Unanimous**
MOTION CARRIED
Meeting adjourned at 1:50p.m.